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SNOWDEN PENCER

Switch-Blade® Disposable Scissor Tips 510K pre-market notification Summary of Safety and Effectiveness

Purpose

This summary is intended to summarize content pursuant to CFR 21 part 807.92 of the Switch-Blade® Scissor Tips 510K Premarket Notification and the results of testing performed to show compliance with stated standards. Additionally the summary is intended to show significant equivalence with the predicate devices listed in this document.

Submitters Information

This Summary was created for Snowden Pencer Inc. on 27 February 2003 by the following individual:

David J. Booth
Snowden Pencer
Director of Quality Assurance and Regulatory Affairs

Contact Info:

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Manufacturers Name, Address and Facility Registration Number

Snowden Pencer Inc.
5175 South Royal Atlanta Drive
Tucker GA 30084

Facility registration number
1038548

Trade Name

Switch-Blade® Curved Metzenbaum Scissors 89-5100
Switch-Blade® Curved Mini-Metzenbaum Scissors 89-5300
Switch-Blade® Hook Scissors 89-5200

Common or Usual Name

Sterile disposable (single use) electrosurgical scissor tip

Device Classification and Code

Class II – electrosurgical cutting and coagulation device and accessory (CFR 21 part 878.4400). Product Code GEI (see attachment III of this section for device listing)

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Predicate Devices

Statement of similarity

The Switch-Blade® remains essentially the same as the previously marketed version of this device in both function and indication for use. The Switch-Blade® is significantly equivalent to the Cooper Surgical (NU-TIP™), Micro Line("RE-NEW"), Aesculap (SOVEREIGN®), and Marlow (NU-TIP™)sterile electrosurgical scissor.

510K Table

The following table identifies the 510K number for the device Snowden Pencer wishes to use as predicate devices for purposes of this submission.

Manufacturer	Cooper Surgical (NU-TIP)	Aesculap (SOVEREIGN®)	Micro Line ("RE-NEW")	Marlow (NU-TIP)**
510K #	Unknown *	K001330	K962119	Unknown **
Product Code Reg #	GCJ 876.1500	GEI 878.4400	GEI 878.4400	

* 510K could not be determined however medical device listing info is provided in attachment I of this section

** NU-TIP™ acquired from Marlow by Cooper Surgical

Description of Device

The Switch-Blade® scissor tip product family consists of three configurations differing only in size and shape. The Switch-Blade® is supplied sterile in an individual Tyvek® pouch; six of these pouches are placed in 6 unit box (i.e. sales unit). The product is intended to be single use and is used in conjunction with catalog numbers 90-1050, 90-1150 or 90-1250 to achieve electrosurgical cutting and coagulation of tissue. The device consists of metal and polymer components.

Indications for Use

Intended Use

The Switch-Blades® product is included in the indications for use of "Endoscopic Electrodes and Electrocautery Instruments" which are intended to be "connected to electrosurgical units via cable to allow monopolar cutting and coagulation". The intended use is contained in the Snowden Pencer Endoscopic Electrodes and Electrocautery Instruments IFU (instructions for use) document # 26-0188. The device IFU is further supplemented with a pictorial IFU contained in the disposable sale unit packaging document # 26 0043. Copies of these documents are provided in attachment II of this document

Technology Characteristics

The Switch-Blade® product functions on the well established methods/characteristics of monopolar high frequency electro-surgery as do all of its listed predicates. The performance/technological characteristics of the Switch-Blade® product and its predicates are dictated by national and international standard (i.e. 60601-2-2, 60601-2-18 and AAMI HF 18(same as 60601-2-18)) and are therefore the same.

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Conclusion

The Switch-Blade® product has a long history of safe and effective performance in the field. The proposed change in design and related change in sterilization method resultant from manufacturing improvement efforts has been fully and/or will be fully validated prior to product release. The Switch-Blade® product has been shown to be significantly equivalent to the aforementioned predicate devices. All testing dictated by various standards related to electrical safety (IEC 60601-2-2 and 606-1-2-18), biocompatibility (ISO 10993) and sterility assurance (11135) have been and/or will be performed prior to product release. (NOTE previous statements regarding have been and/or will be prior to product release refer to sterility assurance activities related to the performance of validations in accordance with ISO 11135 i.e. load 3 testing)

Signed,

2/27/03

David J. Booth
Quality Assurance and Regulatory Affairs Director

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Snowden Pencer, Inc.
c/o Ms. Laura Danielson
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8
New Brighton, Minnesota 55112-1891

Re: K030890
Trade/Device Name: Switch-Blade® Scissor Tips
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Devices
Regulatory Class: II
Product Code: GEI
Dated: March 20, 2003
Received: March 21, 2003

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030890

Device Name: Switch-Blade® Curved Metzenbaum Scissors 89-5100
Switch-Blade® Curved Mini-Metzenbaum Scissors 89-5300
Switch-Blade® Hook Scissors 89-5200

Indications For Use: The Switch-Blade® disposable scissor tips are supplied sterile and are intended for single use. The disposable scissor tips in conjunction with the reusable scissor shaft are intended to be connected to an Electrosurgical Unit via cables to allow high frequency monopolar cutting and coagulation of tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030890

(Optional Format 3-10-98)